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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,263	10/02/2003	Fumihisa Kitawaki	43888-278	3473

7590 09/08/2005

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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/676,263	Applicant(s) KITAWAKI ET AL.	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.  
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-10 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on October 2, 2003 and July 1, 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*12*

Art Unit: 1641

### DETAILED ACTION

Examiner acknowledges Applicants' reply, filed July 1, 2005, which amended claims 1, 3 and 5. Claims 11-22 were withdrawn from consideration pursuant to 37 CFR 1.142(b) in Office Action, dated April 7, 2005, as being drawn to nonelected invention.

Currently, claims 1-10 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Specification*

The amendment filed July 1, 2005, is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. Section 132(a) of 35 U.S.C. states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows:

Applicants' reply, beginning p. 3, line 13, and ending p. 4, line 7 (amending specification paragraph beginning p. 5, line 18), the concomitant removal of "." and addition of "or"

Applicants' reply, beginning p. 5, line 10, and ending p. 6, line 6 (amending specification paragraph beginning p. 7, line 20), the concomitant removal of "." and addition of "or"

Applicants' reply, p. 9, lines 2-3 (amending specification paragraph beginning at page 27, line 26), addition of "handling device 48" (emphasis in original)

Applicants' reply, Replacement Sheet for Fig. 9, addition of reference character "48"

Applicants' reply, p. 10, line 2 (amending specification paragraph beginning at page 30, line 9), the addition of ", either"

Art Unit: 1641

Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is further objected to because of the following informalities:

Throughout the specification, the phrase "is acted" is grammatically awkward because the verb tenses do not agreed.

The paragraph beginning p. 5, line 18 (as amended), is grammatically awkward and indefinite, due to the existence of 25 comma splices, and 8 conjunctions, and one period.

The paragraph beginning p. 7, line 20 (as amended), is grammatically awkward and indefinite, due to the existence of 30 comma splices, and 11 conjunctions, and one period.

Appropriate correction is required.

The abstract of the disclosure is objected to because the phrase "is acted" is grammatically awkward (i.e. the verb tenses do not agreed). Correction is required. See MPEP § 608.01(b).

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because different reference characters are used to designate the same structural details. For example:

reference characters "1" (Fig. 1) and "11" (Fig. 2) are both used to designate "sampling element"

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as

Art Unit: 1641

"amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation of "dynamic effect" lacks antecedent basis and is indefinite because a cause of said "dynamic effect" is not clear. It is not clear whether/how said "dynamic effect" occurs when its cause is not known. In addition, the recitation of "on which a dynamic effect is acted on" is indefinite because it is not clear whether/how "a dynamic effect is acted on". In addition, the recitation of "is acted on" appears grammatically awkward because the verb tenses do not agree. It is not clear what entity is performing action or what object(s) "is acted on".

In claim 5, the recitation of ", or both a1 and b1" is grammatically awkward and indefinite because it is not clear whether the analyte sampling element retains both a1 and b1.

***Claim Rejections - 35 USC § 102***

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (US 6,632,399).

Kellogg et al. teach an analyte sampling element (see Abstract, "apparatus for performing microanalytic and microsynthetic analyses") comprising a first region capable of quantitatively collecting and temporarily retaining an analyte (see Fig. 9, metering capillary 702; col. 5, line 28, "rotors") and a magnetic second region (see col. 6, line 61, "electromechanical means") connected to the first region, on which a dynamic effect (see col. 7, lines 43-44, "monotonic increase in rotational rate", noting inherency of torque) is acted on (noting inherency of Newton's Third Law of Motion) from outside the second region to move (see Abstract, "rotation") said first region.

With respect to claim 3, Kellogg et al. teach an analyte sampling element wherein a change in magnetic field (see col. 6, line 61, "electromechanical means") causes said dynamic effect (see col. 7, lines 43-44, "monotonic increase in rotational rate", noting inherency of torque).

With respect to claims 5-8, Kellogg et al. teach an analyte sampling element further comprising a reagent (see Table I, "Components on solid phase") for reacting with a substance (see Table I, "Assay for:"), and a reagent for destroying a cell (see Fig. 9, "lysis buffer chamber 716", col. 29, line 30, "0.1% Triton X100").

With respect to claims 9-10, Kellogg et al. teach an analyte sampling element wherein said cell is an erythrocyte (see col. 31, line 13, "lysed blood") and said component is hemoglobin (see col. 31, lines 47-50).

***Response to Arguments***

In prior Office Action, Examiner objected to the drawings (Figs. 1 and 4) for failing to comply with 37 CFR 1.84(p)(4) because different reference characters were used to designate the same structural details. In response, Applicants' argue that 37 CFR 1.84(p)(4) does not require the same reference character for similar structural details illustrated in different embodiments of the invention. Applicants' argument with respect to Figs. 1 and 4 is persuasive. Accordingly, the objection to Figs. 1 and 4 under 37 CFR 1.84(p)(4) is withdrawn.

In prior Office Action, claims 1-10 were rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (US 6,632,399). In response, Applicants have amended independent claim 1 to add narrowing limitations. Applicants argue Kellogg et al. do not disclose a device comprising "a magnetic second region, connected to the first region, on which a dynamic effect is acted on from outside of the second region to move the first region" (see Applicants' reply, p. 19, lines 10-13). Applicants' amendment and argumentation have been carefully considered but are not sufficient to overcome anticipation by Kellogg et al. for the reasons set forth supra, *Claim Rejections - 35 USC § 102*.

Art Unit: 1641

**Conclusion**


No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

David J Venci  
Examiner  
Art Unit 1641

djv

  
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05/31/05